REMARKS/ARGUMENTS

In response to the Final Office Action mailed October 16, 2003, Applicants propose to amend their application and request reconsideration in view of the proposed amendments. In this amendment, Claims 1 and 8 are proposed to be amended, Claim 15 was previously cancelled without prejudice and no claims have been added so that Claims 1-14 are currently pending. No new matter has been introduced.

Claims 1-14 were rejected as being unpatentable over U.S. Patent Number 6,214,901 to Chudzik et al. (Chudzik) in view of U.S. Patent Number 5,516,781 to Morris et al. (Morris). This rejection is respectfully traversed.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness.

> "To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d,488,20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria."

Section 2143.03 of the MPEP clarifies certain criteria in section 706.02(j).

> "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1074). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)."

The present invention, as claimed in amended independent Claim 1, is directed to a method for preventing constrictive remodeling, comprising a controlled delivery, by release from a stent, of a compound having anti-proliferative and anti-inflammatory properties in therapeutic dosage amounts, the compound substantially reducing in-lesion lumen loss both proximate and distal to the stent. The dosage ranges from about thirty-five micrograms per fifteen to eighteen millimeters of stent to about four hundred thirty micrograms per fifteen to eighteen millimeters of stent. The present invention, as claimed in amended Claim 8, is directed to a drug delivery device for treating constrictive vascular remodeling. The device comprises a stent and a therapeutic dosage of an agent having anti-proliferative and anti-inflammatory properties releasably affixed to the stent for the treatment of constrictive vascular remodeling. The agent substantially reducing in-lesion lumen loss both proximal and distal to the stent. The agent is incorporated in a polymeric matrix.

In each of these independent claims, the polymeric matrix comprises two layers, wherein the agent or compound is substantially in one layer and the second layer acts as a diffusion barrier. In addition, the total thickness of the polymer matrix is in the range from about one micron to about twenty microns.

Chudzik discloses a coating composition and related method for using the composition to coat an implantable medical device with a bioactive agent in a manner that permits the surface to release the bioactive agent over time when implanted in vive. The composition

comprises a bioactive agent in combination with a plurality of polymers. For a given combination of polymers, the release rate can be adjusted and controlled by adjusting the relative concentrations of the polymers in the coating mixture. The bioactive agents useful in this invention include virtually any therapeutic substance which possesses desirable therapeutic characteristics for application to the implant site. Specifically, the coating composition can be used to coat stents. In one example, the coatings, which contain a mixture of two polymers proved to be very durable with no signs of wear in a durability test and no cracking in the flexibility test.

Morris discloses a method for preventing or treating hyperproliferative vascular disease in a mammal by administering an effective amount of an anti-proliferative (rapamycin) alone or in combination with mycophenolic acid. The delivery method may include the use of a stent. Specifically, Morris discloses the use of rapamycin in preventing smooth muscle cell hyperplasia, restenosis and vascular occlusion resulting from mechanically mediated injury. Essentially, Morris discloses treating or preventing hyperproliferative vascular disease in a mammal by administering an anti-proliferative effective amount of rapamycin to the mammal in any number of ways, including a stent. Morris also discloses the combination of rapamycin and mycophenolic acid to treat the same condition.

As stated above, to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. The references, whether taken alone or in combination, fail to disclose or even suggest the invention of independent Claims 1 and 8. In Chudzik, the polymeric coating is a single layer structure comprising two polymers. In Chudzik, column 3, lines 25-29, Chudzik teaches away from the claimed invention by stating "This obviates the need to control the bioactive release rate by polymer selection, multiple coats or layering of coats..." In the claimed invention, the agent is incorporated into the first layer and the second layer is configured substantially as a diffusion barrier. In addition, neither reference discloses a coating thickness in the range from about one micron to about twenty microns. Therefore, since the references fail to disclose all of the claim limitations, there is no *prima facie* case of obviousness. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1-14 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-11of copending Application Number 09/850,233, Claims 1-15 of copending Application Number 09/850,507, Claims 1-17 of copending Application Number 09/850,232, Claims 1-14 of copending Application Number 09/850,365, Claims 1-15 of copending Application Number 09/575,480 and Claims 1-20 of U.S. Patent Number 6,585,764.

Applicants understand that this rejection is to alert Applicants that an actual rejection on the same ground may be issued if one of the applications ultimately issues. However, in light of the amendments to the claims of the present invention and any potential amendments made to the claims of the cited application, Applicants shall defer any arguments and/or actions until the applications actually issue.

The amendment raises no new issues and places the application in condition for allowance. Therefore, entry is proper and earnestly solicited.

Respectfully submitted,

By:_____

Carl J. Evens
Reg. No. 33,874

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2518
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